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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,676	02/21/2007	Alfonsa Casarotto	06UVB004	4485
39232	7590	02/02/2009	EXAMINER	
Themis Law 7660 Fay Ave Ste H535 La Jolla, CA 92037			DANEGA, RENEE A	
			ART UNIT	PAPER NUMBER
			3736	
			MAIL DATE	DELIVERY MODE
			02/02/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,676	<b>Applicant(s)</b> CASAROTTO ET AL.	
	<b>Examiner</b> Renee Danega	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Barr, Sr. et al. (US 3326206).

- Regarding claims 1-3, Barr, Sr. teaches a process for production of holder and a holder comprising providing a tubular casing and vacuum tube for blood sampling, the casing comprising side and front walls with an opening for housing a needle and further a support wall substantially triangular in shape and extending from the front wall, the support wall having a first side aligned with the front wall and second side aligned with the side wall, the first side being positioned between the opening of the side wall and support wall further comprising a third side connecting the first and second (Figures 1-3, 5); partially inserting the needle in straight shape through the opening in the casing, the needle being affixed to the front wall and having an inner portion coaxial the casing and housed inside the casing and an outer portion extending from the casing and ending with an angled tip facing in the direction of the longitudinal axis of the casing; causing a first bending of the outer portion of the needle to

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slant it with respect to the axis of the casing and to make it contact the third side of the support wall; causing a second bend of the outer portion of the needle to align the terminal outer portion of the needle with the side wall of the casing; and affixing at least a part of the slanted outer portion of the needle to the third side of the support wall and the support wall providing a lower sliding surface for the casing against a patients limb during the introduction of the needle into the limb (column 3, lines 36-52) (column 4, lines 24-47) (column 6, lines 35-40).

- Regarding claim 4, Barr, Sr. teaches the holder wherein the support wall of the casing is provided with a semicircular seat (30) for securely housing the needle (Figure 5) (column 4, lines 24-40).
- Regarding claim 5, Barr, Sr. teaches the end portion of the needle situated outside the casing has an end tip that is slanted and facing in the direction of the longitudinal axis of the casing (42) (Figure 9).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barr, Sr. as applied to claim 2 above, and further in view of Barr, Sr. et al. (US 3520292).

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- Regarding claim 6, Barr, Sr. doesn't expressly teach providing a cap with the holder to cover the needle. However, Barr, Sr. '292 teaches a holder for test tubes in which a cover (22) is provided over the needle tip (18) to maintain sterility (Figures 1-2, column 3, lines 23-30). It would have been obvious in view of Barr, Sr. '292 to provide a cover over the needle in Barr, Sr. in order to maintain sterility.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barr, Sr. as applied to claim 2 above, and further in view of Patrick et al. (US 20040049164).

- Regarding claim 7, Barr, Sr. doesn't expressly teach the holder casing having an indicator of the international code of the needle gauge. However, Patrick teaches an injection device in which the individual components of the device are color coded by industry standard to indicate the needle gauge of the product [0034]. It would have been obvious in view of Patrick to color code the individual components of Barr, Sr. in order to indicate the needle gauge of the device to the assembler and operator.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736